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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,703	11/28/2000	David Botstein	P2533C2	7610

9157 7590 08/29/2002
GENENTECH, INC.
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SOUTH SAN FRANCISCO, CA 94080

EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/29/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/723,703

Applicant(s)

BOTSTEIN ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 24-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Upon further consideration the restriction and species election has been vacated.
2. Claims 1, 3, 24-35 are pending and under examination.

Specification

3. The disclosure is objected to because of the following informalities:
 - a. The Brief Description of the Drawings, pages 4-5, is incomplete as it lacks a separate description for Figures 1A and 1B. The Brief Description of the Drawings need to be amended so that Figures recite separate descriptions for each view that match the labels for the Drawings. Also any reference to the figures in the specification needs to be amended accordingly.
 - b. The use of the apparent trademarks "Taqman" (page 38, line 25) for example, have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.
 - c. The title of the invention is not descriptive. The claims recite no methods for treatment of tumor. A new title is required that is clearly indicative of the invention to which the claims are directed.
 - d. The first line of the specification should be updated to indicate the proper priority and proper status of all applications for which benefit is claimed. The first line of the specification states that the instant application is a CON of 09/234,730 which is a non-provisional application of 09/033,114. The instant application is a DIV of

09/234,730 which is a CIP of 09/033,114. The instant application is not the same as the 09/033,114 application (see for example page 2, lines 30-34 of the instant application which discloses CT-1 is amplified in tumor cells, which is not seen in applications 09/033114).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 3, 24-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1, 3, 24-35 are indefinite for reciting "under stringent conditions" in claim 1 and 28-29 because the exact meaning of the phrase is not clear. The specification on pages 8-9 describes at least 3 "stringent conditions" as well as "high" and "moderately stringent" conditions. As such it is not clear which full set of conditions are encompassed in the claims and as such one can not determine the meets and bounds of the claims.

b. Claim 30 is indefinite for reciting "Stanford Human Genome Center Marker Probes SHGC-1235...." because the exact meaning of the phrase is not clear. It is not clear whether or not these are trademarked or not and if they are trademarked, They

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should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 3, 24-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims encompass detecting the level of expression and the copy number of any gene encoding a CT-1 polypeptide. The specification defines CT-1 polypeptide as "variant forms[] and naturally-occurring allelic variants of CT-1" (see page 8, lines 1-2). The general knowledge in the art concerning variants does not provide any indication of how the structure of one variant is representative of unknown variants. Reiger et al. (Glossary of Genetics and Cytogenetics, Classical and Molecular, 4th Ed., Springer-Verlag, Berlin, 1976) clearly define alleles as one of two or more alternative forms of a gene occupying the same locus on a particular chromosome... and differing from other alleles of that locus at one or more mutational sites (page 17). Thus, the structure of

naturally occurring allelic sequences are not defined. With the exception of SEQ ID NO:3 the skilled artisan cannot envision the detailed structure of the encompassed polypeptides and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.

The claims are drawn to a "gene" or "genes" encoding a CT-1 polypeptide. The specification teaches only the cDNA of SEQ ID NO:1 and the complementary sequence, SEQ ID NO:2 encoding SEQ ID NO:3.

According to Genes IV (Lewin et al, Oxford University Press, page 810, 1990), a gene is defined as "the segment of DNA involved in producing a polypeptide chain; it includes regions preceding and following the coding regions (leader and trailer) as well as intervening sequences (introns) between individual coding segments (exons)." From the teachings of the specification, however, the nucleic acid sequences appear limited to the specific coding regions, and do not include expression control elements that fall under the definition of a gene.

The specification fails to disclose the structural elements of a gene that would encode the DNA sequences, promoter and regulatory regions and introns, and all defining elements of a "gene". The specification lacks information to lead one of skill in the art to understand that the applicant had possession of the broadly claimed invention at the time the instant application was filed.

Claim 28 recites "detecting the number of copies of a nucleic acid marker sequence on the chromosome encoding a cardiotrophin-1 (CT-1) polypeptide". The specification discloses only SEQ ID NO:1 as discussed above and states that this

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nucleic acid maps to chromosome 16 (see page 50, lines 15-16). Therefore, the specification does not disclose any other chromosome location that encodes SEQ ID NO:1 other than chromosome 16.

Thus, one of skill in the art would not understand that the applicant had possession of the claimed invention at the time the instant application was filed.

8. Claims 1, 3, 24-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 28 have been amended in the amendment filed 11/28/02 (amendment B) to recite " a nucleic acid probe comprising at least 20 contiguous nucleic acid bases from DNA 58125 (SEQ ID NO:1) or its complement (SEQ ID NO:2)". The amendment states that support can be found in the original claims and throughout the specification at the recited locations (see page 4 of amendment). The examiner has attempted to locate in the specification where support for this language is found, however, no specific examples or language of a probe limited to at least 20 nucleotides of SEQ ID NO:1 or its complement was found. Applicant is required to specifically provide support for the limitation in the specification as originally filed or remove it from the claims.

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9. Claims 29-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 29 has been amended in the amendment filed 11/28/02 (amendment B) to recite " a nucleic acid probe comprising at least 20 contiguous nucleic acid bases from a sequence, or its complement, in Chromosome 16 from chromosomal regions selected from the group consisting of regions P7...and P208". The amendment states that support can be found in the original claims and throughout the specification at the recited locations (see page 4 of amendment). The examiner has attempted to locate in the specification where support for this language is found. The specification describes the map positions and the Stanford Human Genome Center Marker Name (see Table 3 and Table 6) however, no specific examples or language of a probe limited to at least 20 nucleotides of any probe was found. Applicant is required to specifically provide support for the limitation in the specification as originally filed or remove it from the claims.

10. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and

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failing to provide an enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials.

This rejection is in two parts.

1). If the probes recited in claim 30 are trademarked (see 112 second rejection above) then one cannot practice the invention because the probes are trademarked.

2). If not part 1) above then a deposit of the probes is required to practice the invention absence a showing of public availability or providing the sequence of the probes with evidence that the sequence is of those listed in claim 30.

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of

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this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, appearing to be 'L. Helms', written in a cursive style.